



## Positive New Data for Johnson & Johnson Single-Shot COVID-19 Vaccine on Delta Variant

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## Positive New Data for Johnson & Johnson Single-Shot COVID-19 Vaccine on Activity Against Delta Variant and Long-lasting Durability of Response

*Demonstrated strong neutralizing antibody activity against the Delta (B.1.617.2) variant*

*Persistent immune responses through at least eight months*

**NEW BRUNSWICK, N.J., July 1, 2021** – Johnson & Johnson (NYSE: JNJ) (the Company) today announced data that demonstrated its single-shot COVID-19 vaccine generated strong, persistent activity against the rapidly spreading Delta variant and other highly prevalent SARS-CoV-2 viral variants. In addition, the data showed that the durability of the immune response lasted through at least eight months, the length of time evaluated to date. The two preprint study summaries have been submitted today to *bioRxiv*.

“Today’s newly announced studies reinforce the ability of the Johnson & Johnson COVID-19 vaccine to help protect the health of people globally,” said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. “We believe that our vaccine offers durable protection against COVID-19 and elicits neutralizing activity against the Delta variant. This adds to the robust body of clinical data supporting our single-shot vaccine’s ability to protect against multiple variants of concern.”

“Current data for the eight months studied so far show that the single-shot Johnson & Johnson COVID-19 vaccine generates a strong neutralizing antibody response that does not wane; rather, we observe an improvement over time. In addition, we observe a persistent and particularly robust, durable cellular immune response,” said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. “With each new dataset, we build on our solid foundation of evidence that our single-shot COVID-19 vaccine plays a critical role in ending the pandemic, which continues to evolve and pose new challenges to global health.”

### **Demonstrated strong neutralizing antibody activity against the Delta (B.1.617.2) variant**

A preprint submitted by the Company today to *bioRxiv* contains a new analysis from blood samples obtained from a subset of participants (n=8) in the **Phase 3 ENSEMBLE** study. These data showed that the Johnson & Johnson

single-shot COVID-19 vaccine elicited neutralizing antibody activity against the Delta variant at an even higher level than what was recently observed for the Beta (B.1.351) variant in South Africa where high efficacy against severe/critical disease was demonstrated.

In the ENSEMBLE trial, Johnson & Johnson's single-dose COVID-19 vaccine was 85 percent effective against severe/critical disease and demonstrated protection against hospitalization and death. The vaccine was consistently effective across all regions studied globally, including in South Africa and Brazil, where there was a high prevalence of rapidly emerging Beta and Zeta (P.2) variants during the study period.

### **Immune responses persisted through at least eight months**

Data submitted by Dan Barouch, M.D., Ph.D., of Beth Israel Deaconess Medical Center *et al.*, to *bioRxiv* from a sub-study of the Johnson & Johnson Phase 1/2a COVID-19 vaccine study (n=20) showed that humoral and cellular immune responses generated by the Johnson & Johnson single-shot COVID-19 vaccine lasted through at least eight months, the latest timepoint recorded in the study thus far. Data showed that T-cell responses – including CD8+ T-cells that seek out and destroy infected cells – persisted over the eight-month timeframe examined.

A single dose of the Johnson & Johnson COVID-19 vaccine generated neutralizing antibodies against a range of SARS-CoV-2 **variants of concern**, which increased over time (the average neutralizing titer at eight months exceeded that average at 29 days), including against the increasingly prevalent and more transmissible Delta (B.1.617.2) variant, the partially neutralization-resistant Beta (B.1.351), the Gamma (P.1) variants and others, including the Alpha (B.1.1.7), Epsilon (B.1.429), Kappa (B.1.617.1) and D614G variants, as well as the original SARS-CoV-2 strain (WA1/2020).

### **Johnson & Johnson's single-dose COVID-19 vaccine is now available in many regions and countries on a not-for-profit basis during the emergency pandemic period**

The vaccine received **Emergency Use Authorization (EUA) in the United States** on February 27 and **Conditional Marketing Authorization (CMA)** by the European Commission on March 11, 2021. The World Health Organization (WHO) issued **Emergency Use Listing** on March 12, 2021 and the Company received an **interim recommendation** by the Strategic Advisory Group of Experts (SAGE) on Immunization for the WHO on March 17, 2021. Many more authorizations have been granted in countries worldwide, and regulatory submissions are ongoing.

Research and development activities for the Company's COVID-19 vaccine, including the ENSEMBLE clinical trial and the delivery of doses for the U.S., have been funded in part with federal funds from the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201700018C, and in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS).

Johnson & Johnson has worked with BARDA since 2015 on innovative solutions for influenza, chemical, biological, radiation and nuclear threats and emerging infectious diseases such as Ebola.

### **Storage and Distribution**

The Johnson & Johnson COVID-19 single-dose vaccine is compatible with standard vaccine storage and distribution

channels with ease of delivery to remote areas. The vaccine is estimated to remain stable for two years at -4°F (-20°C), and a maximum of 4.5 months at routine refrigeration temperatures of 36° to 46°F (2° to 8°C). The Company will ship the vaccine using the same cold chain technologies it uses today to transport other medicines. The COVID-19 vaccine should not be re-frozen if distributed at temperatures of 36°F to 46°F (2°-8°C).

For more information on the Company's multi-pronged approach to helping combat the pandemic, visit:

[www.jnj.com/covid-19](http://www.jnj.com/covid-19).

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### **Authorized Use**

The Janssen COVID-19 vaccine is authorized for use in the U.S. under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

### **Important Safety Information**

#### **WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?**

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

#### **WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?**

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction to any ingredient of this vaccine.

#### **HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?**

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle. The Janssen COVID-19 Vaccine vaccination schedule is a single dose.

#### **WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?**

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin, and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, fever.

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic

reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two-weeks following vaccination. Most people who developed these blood clots and low levels of platelets were females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

### **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form. In addition, you can report side effects to Janssen Biotech, Inc. at 1-800-565-4008.

The FDA EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and full EUA Prescribing Information are available at: [www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf](http://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf).

### **About Johnson & Johnson**

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life.

Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at [www.jnj.com](http://www.jnj.com). Follow us at @JNJNews.

### **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at [www.janssen.com](http://www.janssen.com). Follow us at @JanssenGlobal.

### **Cautions Concerning Forward-Looking Statements**

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of a potential preventive vaccine for COVID-19. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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